FOREWORD

The U.S. Army Medical Research and Materiel Command (USAMRMC) has been directed by the Secretary of the Army to administer the Department of Defense (DOD) Neurofibromatosis Research Program (NFRP). The deadlines, format, and other criteria specified for proposals in this Broad Agency Announcement (BAA) are based on program objectives, public needs, and acquisition regulations.

Section I of this announcement summarizes the program focus, award category, funding mechanism, and funding levels. This information is based, in part, on the July 1997 recommendations of the NFRP Integration Panel.

Section II describes the USAMRMC process for scientific and programmatic evaluation and lists evaluation criteria for proposals solicited by this BAA.

Section III provides directions for proposal preparation.

Section IV of this announcement includes instructions for proposal submission (i.e., date, number of copies, where submitted), general information on the USAMRMC's extramural research program, and award administration.

Section V, the Appendices, is a summary of information, some of which must be included with the submitted proposal. All of the issues discussed in the Appendices 1-7 must be addressed before an award can be made.

The NFRP endeavors to ensure that all applicants' ideas are given fair consideration, and that the research that is ultimately funded best meets programmatic goals. Applicants should submit questions in writing as early as possible. However, one should carefully review this announcement before submitting a question. The resources cited in this BAA as well as those available within local institutions (e.g., the Business or Contracts Office) should be fully utilized.

No extensions can be granted to the proposal submission deadlines. Every effort will be made to answer questions within ten working days of receipt. Inquiries must be restricted to format issues only; no questions relating to technical proposal content or reasonableness/ allowableness of costs will be answered.

General information on the USAMRMC can be obtained on the World Wide Web at *http://mrmc-www.army.mil*. Specific information on the DOD NFRP can be obtained at *http://mrmc-rad6.army.mil.* A copy of this BAA and associated forms (not including the proposal cover booklet) can be downloaded at *http://mrmc-rad6.army.mil/documents.html.*

Questions concerning the preparation of proposals, formats, or required documentation can be addressed to the USAMRMC at:

U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (NFRP-BAA-97)
524 Palacky Street
Fort Detrick, MD 21702-5024
Phone: (301)619-7079
Fax: (301)619-7792
E-mail: radvi_baa@ftdetrck-ccmail.army.mil

<u>Proposal Submission Requirements</u>:

Proposal: one original and thirty copies.
Proposal Cover Booklet: one original and two copies.
Technical Abstract Page: additional thirty copies in a manila envelope.

<u>Proposal Submission Address</u>:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (NFRP-BAA-97)
1076 Patchel Street
Fort Detrick, MD 21702-5024

<u>Proposal Deadline</u>:

17 December 1997, 4:00 p.m. Eastern Standard Time

U.S. Army 1997 Neurofibromatosis Research Program
Proposal Acceptance Checklist

Remember to Fax the Proposal Cover Booklet Order Form (blue in color).

The following criteria must be followed. Failure to conform to any of these criteria may lead to rejection of the proposal.

[ ] Completed Proposal Cover Booklet (bubble sheet). You must submit an original booklet plus two copies. The following signatures are mandatory:

- [ ] Principal Investigator (Steering Committee Chairperson)
- [ ] Institution Contracting Representative
- [ ] Official of the Institution (if applicable)

[ ] Main Section: Maximum Page Limits

[ ] Proposal Title Page	1 page
[ ] Table of Contents	1 page
[ ] Proposal Abstract Page	1 page
[ ] Proposal Relevance Statement	1 page
[ ] Body of the Proposal	40 pages
[ ] Statement of Work	2 pages

[ ] Detailed Cost Estimate (using form in Appendix 1) — no page limit

[ ] Addenda

[ ] Addendum A: Acronym and Symbol Definition	2 pages
[ ] Addendum B: Illustrations/Diagrams/Chemical Syntheses	5 pages
[ ] Addendum C: References/Bibliography	5 pages
[ ] Addendum D: Personnel Biographical Sketches	3 pages/investigator
[ ] Addendum E: Existing/Pending Support	no page limit
[ ] Addendum F: Collaboration and Joint Sponsorship	no page limit
[ ] Addendum G: Facilities/Equipment Description	no page limit
[ ] Addendum H: Questionnaires/Clinical Protocols	no page limit
[ ] Addendum I: Publications and Patent Abstracts	5 documents or less

[ ] General Proposal Requirements
  [ ] Is every page single-spaced and single-sided? Double-sided pages may not be accepted (with the exception of article reprints).
  [ ] Margins: Minimum of 0.5 inch top, bottom, right, and left
  [ ] Paper Size: 8.5 inch x 11 inch
  [ ] Type Font: 12 point

[ ] Submit the original proposal plus 30 copies.
  [ ] The original, including the addenda, must be collated and bound with a binder clip.
  [ ] Copies, including the addenda, must be collated and stapled. Do not use binder clips, rubber bands, or spiral/ring binders.

[ ] Submit 30 additional copies of the technical abstract page in a manila envelope.

[ ] Remember: The submission deadline is **17 December 1997 at 4:00 p.m. U.S. Eastern Standard Time**. You must allow time for the proposal to be delivered (see Section IV-B.5 for delivery details). **As in the past, no exceptions will be made for late proposals**.

This checklist is for your use; it does not need to be submitted with the proposal.

TABLE OF CONTENTS

I. AWARD MECHANISM & FUNDING LEVELS

I. AWARD MECHANISM & FUNDING LEVELS

I-A. Overview of the Program

The United States Army Medical Research and Materiel Command (USAMRMC), through this Broad Agency Announcement (BAA), is soliciting proposals in neurofibromatosis research that will provide normative quantitative data on tumor growth in neurofibromatosis patients. The overall goal of this funding effort is to promote research directed toward the understanding, diagnosis, and treatment of neurofibromatosis, and the enhancement of the quality of life for persons with the disease. The objective of the 1997 Neurofibromatosis Research Program (NFRP) is to fund (1) one study to provide normative quantitative data on the growth of plexiform neurofibromas in neurofibromatosis 1 (NF1) patients and (2) one study to provide normative quantitative data on the growth of vestibular schwannomas in neurofibromatosis 2 (NF2) patients. Each proposal should focus on only one research area (NF1 or NF2). It is expected that each study will provide resources from multiple areas such as imaging, pathology, and molecular biology. It is anticipated that the studies will require the formation of a consortium of investigators to ascertain and analyze sufficient numbers of patients to yield the substantial normative data set that will be required for meaningful evaluation of potential therapies. The long-term outcome of these studies will be to provide the capacity for evaluating the efficacy of potential therapies while a by-product of these studies will be the formation of a consortium of investigators with the potential to carry out clinical trials and to expand cooperative research into other clinical manifestations of the diseases.

All proposals will be evaluated in a two-tiered review process consisting of scientific merit review (peer review) in the first tier and programmatic relevance review in the second tier. Although scientific merit is an important requirement for award, proposals that receive high scientific merit scores in peer review but are judged to have low programmatic relevance are less likely to be selected for funding. Therefore, scientifically excellent studies that directly address the unique focus and goals of this program are most likely to receive funding support. The USAMRMC encourages collaborations with minority institutions and proposals addressing the needs of minority, low-income, rural, and other under-represented populations.

I-B. Award Mechanism

Allocation: Approximately $4.2 M

Although the USAMRMC acknowledges an extensive array of needs in neurofibromatosis research, funding for the fiscal year 1997 (FY 97) NFRP will be used to develop natural history studies of tumor growth in NF1 and NF2 that can be readily translated into clinical trials. It is

anticipated that two awards will be made to fund two natural history studies for a maximum four-year period of performance:

- One award to fund a natural history study that will produce quantitative data on growth rates of plexiform neurofibromas in NF1 patients.

- A second award to fund a natural history study that will produce quantitative data on growth rates of vestibular schwannomas in NF2 patients.

Every project must demonstrate:

- a scientifically sound natural history study of normative tumor growth rates of NF1 or NF2 that will produce the substantial data sets necessary to judge the efficacy of future treatments;
- a coherent cost-effective plan for adequate patient accrual for natural history studies with a supporting analysis demonstrating statistical power;
- a comprehensive data management plan;
- standardization of protocol and patient procedures using **commonly accepted** techniques;
- central evaluation of project procedures;
- a multi-institutional and multidisciplinary collaborative effort involving a minimum of two institutions;
- an efficient management plan for the multi-institutional and multidisciplinary collaborative effort; and
- a long term commitment in neurofibromatosis research as evidenced by:
    - consideration of potential for expansion to other clinical manifestations of neurofibromatosis,
    - consideration of potential routes for obtaining follow-on funding, and
    - an organizational structure that allows for the potential addition of collaborators over time.

The intent of the awards is to achieve substantial data on tumor growth rates by funding collaborations among investigators across multiple disciplines and institutions. Consequently, a requirement for consideration will be the formation of a steering committee.

Steering Committee

The steering committee will be composed of the collaborating investigators, clinicians, consumers, and the principal investigator as chair. This committee may expand as the project progresses. A critical determinant of the steering committee's success will be the degree of communication among its members. Therefore, plans for informal meetings among all participants as well as regular telephone and written communication are necessary. It is anticipated that the collaborating investigators will be recruited from, or associated with, other institutions. **Steering committee members may only appear on one submission for NF1 and one submission for NF2.**

Steering Committee Chair/Principal Investigator

The Principal Investigator is the Steering Committee Chair and must be employed by the applicant institution. This person will be responsible for the overall proposed effort.

Advisory Panel

The proposal should recommend individuals to serve on a multidisciplinary advisory panel to provide professional oversight for the project. This independent advisory panel will report directly to the Government and be funded through a separate mechanism. The advisory panel will conduct an in-process review and analysis of the study mid-way through the life of the grant. This review/ analysis will be submitted to the USAMRMC Program Management Team.

I-C. Who May Apply

Proposals are initiated by individuals but are formally submitted by their institutions. Eligible institutions include for-profit and nonprofit organizations, public and private, such as universities, colleges, hospitals, laboratories, and agencies of local, State, and Federal governments. Collaborations with independently funded research groups are encouraged to foster additional networking and growth. Each institution can submit only one NF1 proposal and one NF2 proposal. The Principal Investigator and principal consortium site must be U.S. based, but institutional collaborations, including foreign collaborations, are highly encouraged. Any individual, regardless of nationality or citizenship status, may apply as long as he/she is employed by an eligible institution. Investigators are cautioned that awards are made to institutions and that should a Principal Investigator move during the period of funding, transfer of the award is not guaranteed. Sub-awards by the original recipient institution may be considered.

II. PROPOSAL EVALUATION

II. PROPOSAL EVALUATION

The USAMRMC utilizes a two-tiered review system for proposal evaluation involving separate phases for scientific merit review and programmatic review. The two tiers of review are fundamentally different. Scientific merit review is a criterion-based process in which individual proposals are evaluated for scientific and technical merit without regard to other proposals under consideration. In contrast, programmatic review is a comparison-based process in which proposals from multiple disciplines compete in a common pool. The evaluation of programmatic relevance during programmatic review involves direct comparisons of proposals that are judged to have high scientific merit in peer review. In order for a proposal to be funded, it must be recommended by both levels of the two-tiered review system.

II-A. Scientific Review Panels

Composition and responsibilities: The first level of review will be conducted by a multidisciplinary scientific peer review panel. The primary responsibility of the scientific peer review panel is to provide unbiased, expert advice to the USAMRMC on the scientific and technical merit of applications with respect to the review criteria articulated in this BAA. Given the expected complexity and multidisciplinary nature of proposals for this program, one multidisciplinary review panel will be constituted. The scientific review panel will include an executive secretary, a chairperson, scientific reviewers across the full range of disciplines relevant to neurofibromatosis, and two neurofibromatosis consumer advocates. The executive secretary is the only non-voting member. The scientific reviewers are recognized leaders in their fields and are chosen on the basis of relevant scientific expertise. Selection of the executive secretary and scientific reviewers is predicated upon their individual experience in scientific peer review. Consumer advocates (defined as individuals living with neurofibromatosis or family members of affected individuals) augment scientific merit review by broadening the perspective brought to the assessment of science. A list of all scientific panel members will be released after all awards are negotiated. However, to ensure the confidentiality of the scientific review process, information regarding specific proposal assignments will not be released.

II-B. Scientific Peer Review Evaluation Criteria for Awards

Evaluation Description: First, each proposal will be evaluated according to the criteria listed on page 10. Each evaluation criterion, with the exception of budget, will be rated on a scale of 1 (low

merit) to 10 (high merit). Criteria scoring ensures that each component criterion is considered in the review.

Evaluation Criteria:

a. Scientific quality and research strategy for the project including statistical analysis

b. Standardization of data collection and criteria for disease and tumor diagnosis

c. Feasibility and cost-effectiveness of patient accrual plan

d. Protocol design to include patient sample size, diversity, and plans to ensure patient compliance

e. Qualifications and experience of the Steering Committee and Principal Investigator

f. Quality of management plan

g. Adequacy of resources and environment to support the project

Although it is not an evaluation criterion, project duration and cost is considered and a budget recommendation is provided for all proposals. The panel determines whether the requested budget is realistic and appropriate for the conduct of the proposed research. If budget changes are recommended, justifications are described. If any part of a research project does not merit support, the panel may recommend its deletion. The budget will be adjusted accordingly, and the priority score will then based on the modified project.

In addition, after discussion of a project by the review panel, the proposal will be given a global score based on the adjectival descriptors listed below. The criteria scores will not be averaged or manipulated to determine a priority score; instead, reviewers will use the criteria scores as a guide in determining a priority score.

Scoring Scale	
Outstanding	1.0 - 1.5
Excellent	1.6 - 2.0
Very Good	2.1 - 2.5
Good	2.6 - 3.5
Acceptable	3.6 - 5.0

II-C. The Integration Panel and Programmatic Review

Programmatic review is a comparison-based process in which scientifically meritorious proposals compete in a common pool. Programmatic relevance is an assessment that balances the risks and potential outcomes of scientifically excellent proposals to best fulfill the NFRP goals and objectives. The Integration Panel (IP) does not automatically recommend funding for all highly scored proposals reviewed by scientific peer review panels, nor does it re-review the scientific and technical merit. Instead, it carefully scrutinizes each proposal in an attempt to allocate, as wisely as possible, the funds available for the 1997 NFRP.

Composition and Responsibilities: The ten-member IP for the 1997 NFRP consists of a diverse group of basic and clinical scientists and consumers. The scientific members represent diverse disciplines and specialty areas and are experienced with peer review procedures. Consumer advocates participate in all phases of the IP deliberations. With their first-hand experience, the consumer advocates enhance the review process by focusing attention upon critical patient issues and outcomes. Consumer advocates have also been instrumental in raising public awareness and interest in supporting neurofibromatosis research.

Evaluation: The factors that the IP will consider when making funding recommendations are:

a. Ratings and recommendations of the peer review panels
b. Potential for providing the tumor growth data necessary for evaluating future clinical trials
c. Long-term impact of the project on the understanding and treatment of NF1 or NF2

Although final program authority rests with the Commanding General of the USAMRMC, due consideration will be given to the recommendations provided by the IP.

II-D. Award Notification

Following completion of the two-tiered evaluation process, every Principal Investigator who submits a compliant proposal will receive a letter indicating their funding status, along with a scientific review summary of their proposal. Scientific review summaries will contain the proposal global score and the individual evaluation criteria scores, along with detailed comments about the proposal's strengths and weaknesses with respect to each evaluation criterion. It is expected that this information will be distributed by May 1998. All award negotiations will be completed by 30 September 1998.

III. PROPOSAL PREPARATION

III. PROPOSAL PREPARATION

III-A. Proposal Requirements

Proposals submitted in response to this BAA must conform to the order, length, and format prescribed in this section. Proposals that exceed the page limitations, do not include an original Proposal Cover Booklet, and/or do not contain the prescribed contents and signatures MAY NOT RECEIVE FURTHER CONSIDERATION. Proposals that are received late WILL NOT RECEIVE FURTHER CONSIDERATION.

Proposals shall contain five principal parts:

1. Proposal Cover Booklet (bubble sheet)
2. Main Section
3. Detailed Cost Estimate
4. Addenda
5. Appendices (to be submitted upon request)

Length requirements for these parts are indicated in the Specific Instructions section (see Section III-B).

With the exceptions of the Proposal Cover Booklet, the Questionnaire/Clinical Protocols addendum, and the Publications and Patent abstracts addendum, **all components** of the proposal, to include figure legends, cost estimates, biographical sketches, etc., must:

1. be single-spaced,
2. be submitted on single-sided 8.5" x 11" pages,
3. have margins no less than 0.5 inches,
4. have font no smaller than 12 point, and
5. be written in English.

The following paragraph provides an example of the minimum font size, margins, and spacing:

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Use the Proposal Acceptance Checklist (pages iii-iv) to verify that all proposal acceptance criteria have been met, but do not submit this checklist with the proposal.

An original plus 30 collated copies of the proposal are required. The proposal original should be marked "Original" in the upper right corner. The original copy should not be stapled but should be bound with binder clips. The additional 30 copies should be stapled.

Inclusion of Women and Minorities in Clinical Studies: Women and minorities must be included in all *appropriate* USAMRMC-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling justification establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This information should be included in human use documentation, as described in Appendix 5 of this BAA. Please note, however, that the human use documentation is not to be submitted with the proposal, but must be immediately available upon USAMRMC request (approximately February 1998).

Ordering Additional Proposal Cover Booklets: Additional cover booklets can be obtained by faxing your request to (301)682-5521. On the Proposal Cover Booklet Order Form, include a brief description of the proposed research. Once this form is received, you will be sent two original Proposal Cover Booklets. Proposals will not be accepted without an original and two copies of the Proposal Cover Booklet. *Note: If you do not receive your booklets within ten working days of request, re-order by calling (301)682-5501.*

III-B. Specific Instructions

The following four parts are **required** in the original proposal submission and should be included in the following order:

Principal Parts	Section
1. Proposal cover booklet (bubble sheet)	Section III-B.1
2. Main section	Section III-B.2
3. Detailed cost estimate	Section III-B.3
4. Addenda	Section III-B.4

III-B.1. Proposal Cover Booklet

Two original booklets will be mailed upon receipt of the Proposal Cover Booklet Order Form. You must submit an original and two copies of the Proposal Cover Booklet. The Proposal Cover Booklet must be filled out carefully and completely to ensure that each proposal is assigned to the appropriate review panel. Additional booklets can be requested by:

Fax: (301)682-5521
Phone: (301)682-5501

E-mail: radvi_baa@ftdetrck-ccmail.army.mil
Mail: Commander, U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (NFRP-BAA-97)
524 Palacky Street
Fort Detrick, MD 21702-5024

Allow sufficient time for delivery by regular mail.

ATTENTION: **In order to facilitate the processing of the proposal, it is extremely important that you *read and follow these instructions completely* as you are filling out the Proposal Cover Booklet. Take special care to ensure that the written and bubbled figures match exactly.**

Below are the specific instructions for completing the **Proposal Cover Booklet**.

1. **Proposal Log Number.** (Official Use Only). Leave blank.

2. **BAA Identifier.** Fill out with **"NFRP-97."**

3. **Organization Code.** (Official Use Only). Leave blank.

4. **Organization Name and Address.** Indicate the name and address of the organization that is submitting the proposal on the Principal Investigator's behalf. This is the address for the **Contracting/Business Office** of the Principal Investigator's organization. It is the address for the administrative official indicated in Question 36 who is authorized to conduct negotiations on the applicant's behalf.

5. **Type of Organization.** Choose one primary type and all applicable subtypes within that primary type from the list provided in the Proposal Cover Booklet.

6. **Principal Investigator Last Name, First Name, and Middle Initial.** Fill in the name of Principal Investigator, the individual who is primarily responsible for the overall proposed effort.

7. **Title.** Indicate the appropriate title for the Principal Investigator.

8. **Rank.** Federal employees must fill out their rank completely. If the Principal Investigator is not a Federal employee, leave this blank.

9-15. **Principal Investigator's Mailing Address.** Fill out the Principal Investigator's correct mailing address. This is the address where the work will be performed. **Do not use the Principal Investigator's home address.** If applicable, state the Principal Investigator's organization and department, then street address. Do not use abbreviations or acronyms

of any kind in the address. Do not use formal terms such as "The" or "The Trustees of " when indicating the organization. Where no organization or department name is necessary, fill out the applicant's street address only. If possible, avoid the use of PO Boxes.

16-17. **Principal Investigator's Phone and Fax numbers.** Indicate the Principal Investigator's phone and fax numbers. U.S. phone numbers must be filled in completely.

18. **Principal Investigator's E-mail Address.** If the Principal Investigator has access to e-mail, write the address in the space provided.

19. **Demographics.** (Optional). Indicate the Principal Investigator's gender and ethnicity, if desired.

20. **Degree.** Indicate all that apply.

21. **Proposal Title.** Enter the title of the proposal. This may be up to 160 characters long. Capitalize the initial word and the first letter of each subsequent word, with the exception of prepositions and articles. Please note that each blank space is equivalent to one character.

22. **Total Funding Requested.** Fill in the total dollar amount requested. This is the total dollar amount for all direct and indirect costs for the entire period of the research as indicated in the Budget for Entire Proposed Period of Support (Section III-B.3.i). Enter amounts in whole U.S. dollar figures only. Please be sure to right justify the amount; any blank spaces should be to the left of the amount.

23. **Military/Civilian Collaboration.** Indicate whether the proposal DOES or DOES NOT involve a military/civilian collaboration. If the proposal DOES represent a military/civilian collaboration, fill in the full name and address of the collaborating organization. Note that the lead partner is the non-DOD organization. Therefore, the military organization should be listed here as the collaborating organization.

24. **Human Subjects and Anatomical Specimens.** (Official Use Only). Leave blank.

25. **Number of Human Subjects.** (Official Use Only). Leave blank.

26. **Animal Subjects.** (Official Use Only). Leave blank.

27. **Number of Animal Subjects.** (Official Use Only). Leave blank.

28. **Safety Provisions.** (Official Use Only). Leave blank.

29. **Proposal Category.** Select the ONE code listed below that applies to the proposal and enter it in the space provided.

Type of Award	**Code**
NF1 Natural History Study	10
NF2 Natural History Study	20

30. **Mentor Name.** Leave Blank.

31. **Research Classification.** Leave blank.

32. **Primary Research Area.** Leave blank.

33. **Secondary Research Area 1.** Leave blank.

34-35. ***If the proposed research involves human subjects, answer questions 34 & 35.***

34. **Secondary Research Area 2.** Does the proposed research target one or more of the following minority populations: African-American, Asian, Hispanic/Latino, Native-American, or Pacific Islander?

    Please use the following codes to answer this question:
    If the proposed effort **has** such a plan, use code **100.**
    If the proposed effort **does not have** such a plan, use code **200.**

35. Specifically, does the project have a **planned outreach effort** to recruit and retain minority populations in the study? The goal of such an effort is to develop appropriate lines of communication and to build mutual trust so that both the study and minority communities benefit from the collaboration.

    Please use the following codes to answer this question:
    If the proposed effort **has** such a plan, use code **100.**
    If the proposed effort **does not have** such a plan, use code **200.**

36-38. **Signatures:** This section is mandatory and must be filled out completely. Failure to complete it may result in rejection of the proposal.

36. **Administrative Representative Authorized to Conduct Negotiations.** Indicate the primary and secondary administrative contacts authorized to conduct negotiations on the Principal Investigator's behalf. The address for the primary contact must be indicated in question 4 on the first page of the Proposal Cover Booklet. If the organization has a Contracting/Business Official, this is the authorized individual contacted to negotiate potential awards. The signature of the institutional representative certifies that the offeror

(sponsoring institution) has examined the Principal Investigator's credentials and verifies that the Principal Investigator is qualified to conduct the proposed study and to use humans and/or animals as research subjects (if appropriate). **THIS SIGNATURE IS MANDATORY.**

37. **Official of the Institution.** In cases where the individual in question 36 is not officially authorized to offer the proposal, this signature is mandatory. Please obtain the appropriate certifying signature in this block.

38. **Principal Investigator.** The Principal Investigator must sign in the space indicated. **THIS SIGNATURE IS MANDATORY.**

Check this cover booklet carefully for mistakes before sending it with the proposal. If you have any questions about the NFRP, the BAA, or the Proposal Cover Booklet, please e-mail: radvi_baa@ftdetrck-ccmail.army.mil, or call: (301)619-7079.

III-B.2. Main Section (not to exceed 46 pages; font and margin requirements apply)

The Main Section should contain the following categories:

Proposal Contents:	Section:
A. Proposal Title Page	Section III-B.2.a
B. Table of Contents	Section III-B.2.b
C. Proposal Abstract Pages	Section III-B.2.c
D. Proposal Relevance Statement	Section III-B.2.d
E. Body of the Proposal	Section III-B.2.e
F. Statement of Work	Section III-B.2.f

III-B.2.a. Proposal Title Page - 1 page only (font and margin requirements apply)

A Proposal Title Page must accompany every proposal submission and must include the following information:

1. Principal Investigator's Full Name, including middle initial
2. Proposal Title
3. Organization Name and Location to include city and state
4. Principal Investigator's Phone Number, Fax Number, and E-mail Address
5. Contracting Representative's Name
6. Contracting Representative's Phone Number, Fax Number, and E-mail Address

III-B.2.b. Table of Contents - 1 page only (font and margin requirements apply)

Prepare a Table of Contents, with page numbers, following the outline entitled "Proposal Contents" below. Each category of information specified should be included. Number pages consecutively at the bottom of each page, beginning with the Proposal Title Page, throughout the entire application.

Proposal Contents	Page
A. Proposal Title Page	page 1
B. Table of Contents	page 2
C. Proposal Abstract Page	page 3
D. Proposal Relevance Statement	page 4
E. Body of Proposal	pages 5-44
F. Statement of Work	pages 45-46

III-B.2.c. Proposal Abstract Page - 1 page only (font and margin requirements apply)

A one-page technical abstract of the proposed research must precede the body of the proposal. Note that abstracts of all funded proposals will be reproduced for public distribution in an NFRP abstract book and posted on the Internet. Abstracts shall contain the following items:

1. Title of the Proposal
2. Principal Investigator's Name
3. Up to Five Key Words Relevant to the Proposal
4. Abstract

III-B.2.d. Proposal Relevance Statement - 1 page only (font and margin requirements apply)

In no more than one page, describe how the overall integrated effort will have a substantial impact on neurofibromatosis research and the lives of those living with the disease.

III-B.2.e. Body of the Proposal - up to 40 pages total (font and margin requirements apply)

A concise description of the strategy to form and administer the consortium must be included. The following general outline should be followed:

1. Background
2. Methods
3. Key Personnel and Performance Sites
4. Management Plan

1. Background: This section must provide a review of (1) the current understanding of the natural history of NF1 plexiform neurofibromas or NF2 vestibular schwannomas; (2) the factors that may affect tumor growth; and (3) the *in vivo* imaging technologies necessary for effective *in vivo* measurement of tumor growth rates.

2. Methods: It is anticipated that the measurement of tumor growth will require standardized prospective application of an *in vivo* imaging technique. Analyses are encouraged from other resources such as pathology and molecular biology. Additional data may be obtained by consistent analyses of retrospective data. The methodology used for data collection and analysis should be described in detail. **Methods should be commonly practiced techniques. It is not the program's intent to fund projects that are investigating novel or experimental approaches.** Include standardized criteria for disease, tumor diagnosis, and specific methods of data collection and management across and within institutions. Be sure to demonstrate how standardization of these tasks will be carried out at more than one location. Provide a careful description of data analysis, which should be carried out centrally to ensure efficiency and consistency. Indicate whether additional tasks will be centralized. The study plan should include a description of the number and types of patients to be studied and quantitative patterns of tumor growth.

3. Key Personnel and Performance Sites: Provide an organizational chart to include the Principal Investigator and steering committee, showing the names, institutions/organizations, scientific disciplines, and interrelationships of the members. Delineate how each member is integrated and contributes to the accomplishment of the project. It is recommended that the project include the following expertise: a radiologist, a statistician/data manager, a pathologist, two clinicians, and a consumer. A minimum of two institutions should be included.

4. Management Plan: At a minimum the management plan shall include:
   - a patient accrual plan
   - quality control of data collection procedures
   - a data management plan
   - standardization of disease criteria, diagnosis, data collection, and data management
   - centralization and standardization of data analysis
   - consortium communication and training procedures
   - integration, retention, and dismissal of consortium members, as necessary
   - a description of the potential to carry out future clinical trials or to extend research into other features of NF1 or NF2
   - consideration of potential routes for follow-on funding

III-B.2.f. Statement of Work - 2 pages only (font and margin requirements apply)

The Statement of Work is a concise restatement of the project that outlines and establishes the Principal Investigator's performance expectations for which the USAMRMC will provide support. While some allowance is made for encountering problems and uncertainties that are a part of research, the Principal Investigator is expected to meet the provisions and milestones of the Statement of Work.

Every project submitted in response to this BAA must contain a Statement of Work, in outline form, prepared by the proposer. A series of relatively short statements should be included that comprise the stepwise approach to each of the major goals or objectives of the proposed research. As appropriate, the Statement of Work should:

- describe work to be accomplished as specific tasks;
- identify the timeline and milestones for the work over the period of the proposed effort;
- identify methods (do not describe in detail); and
- identify products/deliverables for each phase of the project.

As a guide, the Statement of Work for a three-year effort should require approximately one page of single-spaced typing. Several sample Statements of Work are included as Appendix 8 of this BAA.

III-B.3. Detailed Cost Estimate

The USAMRMC has introduced a budget sheet to assist in the preparation of detailed cost estimates and to facilitate the review of budgets during proposal evaluation. This form, included as Appendix 1 of this BAA, is the only form that should be used for preparing cost estimates and can be downloaded from the following World Wide Web site: http://mrmc-rad6.army.mil/documents.html. **Please be advised that submissions containing budget forms other than the USAMRMC budget sheet may not receive further consideration.**

Each item in the budget must be clearly justified on the *Justification* page (page 3 of the budget sheet). Further, itemize all budget categories for additional years of support on the *Justification* page. All amounts must be in U.S. dollars. For projects with a substantial foreign component, explain and justify this on the *Justification* page.

An estimate of the total individual project cost, with a breakdown of direct and indirect costs by category and year, must accompany each project description. Note that the cost for the advisory panel will be funded through a separate mechanism. Costs for multiple-year projects should cover the total estimated duration of the project. Costs proposed must conform with the following regulations and principles:

- Commercial Firms: Federal Acquisition Regulations (FAR) Part 31 and Defense FAR Supplement Part 31, Contract Cost Principles and Procedures.

- Educational Institutions: OMB Circular A-21, Cost Principles for Educational Institutions.

- Nonprofit Organizations: OMB Circular A-122, Cost Principles for Nonprofit Organizations.

- OMB Circular A-110, Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations.

- OMB Circular A-133, Audits of Institutions of Higher Education and Other Nonprofit Organizations.

The cost of preparing proposals in response to this BAA is not considered an allowable direct charge to any resultant grant or contract. It is, however, an allowable expense to the bid as a proposal indirect cost specified in FAR 31.205-18 and OMB Circulars A-21 and A-122.

The following costs must be estimated in the detailed cost estimates (use standard budget sheet, Appendix 1 of this BAA):

1. Personnel Costs
   a. Role on Project
   b. Type of Appointment/Months
   c. Percent of Effort on Project
   d. Salary Requested
   e. Fringe Benefits
   f. Totals
2. Consultant Costs
3. Major Equipment Costs
4. Materials, Supplies, and Consumables Costs
5. Travel Costs
6. Research-Related Patient Costs
7. Other Expenses
8. Indirect Costs (overhead, general and administrative, and other)
9. Budget for Entire Proposed Period of Support (Second Budget Page)

III-B.3.a. Personnel Costs

Show projected salary amounts in terms of annual salary and percent effort on the project to be charged by each staff member on the project. Starting with the Principal Investigator, list the names of all employees of the applicant who are involved in the project during the initial budget

period, regardless of whether salaries are requested. Include all collaborating investigators, individuals in training, and support staff.

Role on Project: Identify the role of each individual listed on the project. Describe their specific functions on the *Justification* page (page 3 of the budget sheet).

Type of Appointment/Months: List the number of months per year reflected in an individual's contractual appointment to the offering organization. **DOD staff assume that appointments at the applicant organization are full time for each individual.** If an appointment is less than full time, e.g., 50 percent time, identify this with an asterisk (*) and provide a full explanation on the *Justification* page (page 3 of the budget sheet). Individuals may have split appointments, e.g., for an academic period and a summer period. For each appointment, identify and enter the number of months on separate lines.

Percent of Effort on Project: For each key staff member identified on the budget sheet, list the percent of each appointment to be spent on this project.

Salary Requested: Enter the dollar amounts for each position for which funds are requested. The salary requested is calculated by multiplying the individual's institutional base salary by the percent of effort on the project.

Fringe Benefits: Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors.

Totals: Calculate the totals for each position and enter these as subtotals in the columns indicated.

III-B.3.b. Consultant Costs

Whether costs are/are not committed, provide the names and organizational affiliations of all consultants, other than those involved in consortium arrangements.

III-B.3.c. Major Equipment Costs

It is the policy of the DOD that all commercial and nonprofit recipients provide the equipment needed to support proposed research. In those rare cases where specific additional equipment is approved for commercial and nonprofit organizations, such approved cost elements shall be separately negotiated.

III-B.3.d. Materials, Supplies, and Consumables Costs

A general description and total estimated cost of expendable equipment and supplies are required. Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than $1,000 do not have to be itemized. If animals are to be purchased, state the species and the number to be used.

III-B.3.e. Travel Costs

List the number of trips, destinations, and purposes for all proposed travel. Estimate round-trip fare and per diem costs for each trip. Travel to scientific meetings requires identification of the meeting and purpose. Typically only one trip to a scientific meeting per project is funded per year, it is understood that additional travel expenditures may be required in support of the consortium. Itemize travel requests and justify them on the *Justification* page (page 3 of the budget sheet).

III-B.3.f. Research-Related Patient Costs

Itemize costs of patient participation, if applicable, in the project. These costs are strictly limited to expenses specifically associated with the proposed study. The USAMRMC will not provide funds for ongoing medical care costs that are not related to a subject's participation in the research study.

III-B.3.g. Other Expenses

Itemize other anticipated direct costs such as publication and report costs, rental for computers and other equipment (giving hours and rates), communication costs, etc. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution. Note that the cost for the advisory panel will be funded through a separate mechanism.

III-B.3.h. Indirect Costs (overhead, general and administrative, and other)

The most recent rates, dates of negotiation, base(s), and periods to which the rates apply must be disclosed and a statement included to identify whether the proposed rates are provisional or fixed. A copy of the negotiation memorandum should be provided. If negotiated forecast rates do not exist, sufficient detail must be provided to enable a determination that the costs included in the

forecast rate are allocable. Disclosure should be sufficient to permit a full understanding of the content of the rate(s) and how they were established. As a minimum, the submission should identify:

1. all individual cost elements included in the forecast rate(s);

2. the basis used to prorate indirect expenses to cost pools, if any;

3. how the rate(s) were calculated; and

4. the distribution basis of the developed rate(s).

III-B.3.i. Budget for Entire Proposed Period of Support (Second Budget Page)

Enter the totals under each budget category for all additional years of support requested and itemize these totals on the *Justification* page. Identify with an asterisk and justify any significant increases or decreases from the initial year's budget. Also, justify budgets with a higher than standard escalation from the initial to the future year(s) of support.

III-B.4. Addenda

Proposals that fail to adhere to specified page limits, are incomplete, and/or contain unrequested material may be rejected. Include only the following items in the addenda:

1. Acronym and Symbol Definition	no more than 2 pages
2. Illustrations/Diagrams/Chemical Syntheses	no more than 5 pages
3. References/Bibliography	no more than 5 pages
4. Personnel Biographical Sketches	3 pages per investigator
5. Existing/Pending Support	no page limit
6. Collaboration and Joint Sponsorship	no page limit
7. Facilities/Equipment Description	no page limit
8. Questionnaires/Clinical Protocols	no page limit
9. Publications and Patent Abstracts	no more than 5 documents

Include only items appropriate to the proposal. Note that page limitations apply as indicated. **Use of addenda to continue providing specific written details of the experimental design or methodology may result in rejection of the proposal.**

III-B.4.a. Acronym and Symbol Definition - up to 2 pages (font and margin requirements apply)

Provide a glossary of all acronyms and symbols.

III-B.4.b. Illustrations/Diagrams/Chemical Syntheses - up to 5 pages (font and margin requirements apply)

ONLY figures, tables, diagrams, and chemical syntheses *with minimal figure legends* may be included in this addendum. **Note that tables, legends, and captions must conform to font and margin requirements.**

III-B.4.c. References/Bibliography - up to 5 pages (font and margin requirements apply)

List the references in the order they appear in the proposal narrative. Use a reference format that gives the title of the citation.

III-B.4.d. Personnel Biographical Sketches - 3 pages per investigator (font and margin requirements apply)

Provide a biographical sketch for the Principal Investigator responsible for direction and oversight of the overall effort using the form "Biographical Sketches" provided as Appendix 2 of this BAA. Biographical sketches should also be prepared for each collaborating investigator and must not exceed three pages per investigator. A list of significant publications should be incorporated into the biographical sketches. Curricula vitae that exceed this limit must not be included.

The qualifications of the Principal Investigator and the amount of time that he/she will devote to the overall effort are important factors affecting the selection of proposals. Grants, cooperative agreements, and interagency agreements may be terminated when the Principal Investigator severs connections with the organization or is unable to continue active participation in the research.

III-B.4.e. Existing/Pending Support - no page limit (font and margin requirements apply)

List on a separate page, the titles, time commitments, supporting agencies, durations, and levels of funding for all existing and pending research projects involving the Principal Investigator and key personnel. Where the projects overlap or parallel the current proposal, provide justification for the USAMRMC's interest and support.

III-B.4.f. Collaboration and Joint Sponsorship - no page limit (font and margin requirements apply)

Provide letter(s) from proposed collaborating individuals and institutes (for each individual project element) confirming collaborative efforts that are necessary for the project's success. Describe present or prospective joint sponsorship of any portion of the project outlined in the proposal. In the absence of agreements among sponsors for joint support, the proposal should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal is submitted, information should be sent at the time that the appendices are requested (on or about 1 February 1998).

Prior approval of both agencies must be secured for research to be undertaken under joint sponsorship.

III-B.4.g. Facilities/Equipment Description - no page limit (font and margin requirements apply)

Describe the facilities available for performance of the proposed research and any additional facilities or equipment proposed for acquisition at no cost to the USAMRMC. Indicate if Government-owned facilities or equipment are proposed for use.

III-B.4.h. Questionnaires/Clinical Protocols - no page limit (NO font or margin requirements apply)

Attach questionnaires, survey instruments, or clinical protocols as they apply to the proposal.

III-B.4.i. Publications and Patent Abstracts - no more than 5 documents (NO font or margin requirements apply)

You may include relevant publication reprints and patent abstracts, up to a total of five documents.

III-C. Appendices

The following appendices must be prepared where appropriate for each individual project element. They are NOT to be included with the initial submission but must be immediately available upon USAMRMC request on or about 1 February 1998. Failure to respond may result

in an award not being made. A complete Proposal Title Page (see Section III-B.2.a) must accompany these appendices. The forms required to complete these appendices can be downloaded at the following World Wide Web site: *http://mrmc-rad6.army.mil/documents.html*.

1. Regulatory Compliance Checklist/Form (use form in Appendix 3 of this BAA)
2. Certificate of Environmental Compliance (use form in Appendix 4 of this BAA)
3. Research Involving Human Subjects and/or Human Anatomical Substances (see Appendix 5 of this BAA)
4. Research Involving Animals (see Appendix 6 of this BAA)
5. Safety Program Plan (see Appendix 7 of this BAA)

III-C.1. Regulatory Compliance Checklist/Form

This form, found in Appendix 3 of this BAA, must be completed and sent in when appendices are requested.

III-C.2. Certificate of Environmental Compliance

The certificate found in Appendix 4 of this BAA, must be executed by the institution's official responsible for environmental compliance.

The Council on Environmental Quality (CEQ) regulations (40 CFR 1500-1508) that implement the National Environmental Policy Act (NEPA) (PL 91-190, as amended) require all Federal agencies to examine possible environmental consequences of their proposed and ongoing actions.

The USAMRMC examines all medical research and development projects, whether inside or outside the U.S., for their potential environmental impacts. In most cases, contractors conducting research in established laboratories that are in compliance with environmental laws and regulations, or are already covered by existing environmental documentation, will not be required to provide additional information about the environmental impact of their proposed research. Such projects will receive a "categorical exclusion" according to Army regulations (AR 200-2) that implement the CEQ regulations.

After a proposal has been selected for award, the USAMRMC will determine if a categorical exclusion is warranted. If there are any extraordinary circumstances surrounding the research (e.g., research that involves the transfer of recombinant DNA molecules into the genome of one or more human subjects, requires BSL3 or BSL4 safety levels, or uses animals captured from the wild), further information may be requested to allow a determination of the environmental impact of the proposed research to be made. This information must be submitted in a timely manner in order to receive an award.

III-C.3. Research Involving Human Subjects and/or Human Anatomical Substances

Address all pertinent issues relating to the use of human subjects and anatomical substances in the proposed research. Include the required approvals, forms, and descriptions as outlined in Appendix 5 of this BAA.
Note that Department of Defense rules for participation of human subjects and informed consent differ from those required by other funding agencies.

III-C.4. Research Involving Animals

Address all pertinent issues relating to the use of animals in the proposed research. Include the required assurances, approvals, forms, and descriptions as outlined in Appendix 6 of this BAA. (Research conducted under sponsorship of the USAMRMC that generates preclinical safety data intended to support a research or marketing permit for products regulated by the Food and Drug Administration will be in conformance with the Good Laboratory Practices Regulations.)

Note that Department of Defense procedures for reviewing and approving the use of animals in research differ from those required by other funding agencies.

III-C.5. Safety Program Plan

Address all pertinent issues and include the required assurances, approvals, forms, and descriptions relating to safety as outlined in Appendix 7 of this BAA.

IV. GENERAL INFORMATION

IV. GENERAL INFORMATION

IV-A. Policy and Procedures

IV-A.1. USAMRMC Award

The USAMRMC implements its extramural research program predominantly through the award of grants and cooperative agreements. Proposals selected for funding are processed by the U.S. Army Medical Research Acquisition Activity (USAMRAA).

All awards are made to organizations, not individuals. A Principal Investigator must submit a proposal through, and be employed by, a university, college, nonprofit research institute, commercial firm, or Government agency in order to receive support.

Collaborative research efforts between civilian research institutions and military medical treatment facilities and/or laboratories are encouraged. Information regarding proposed military/civilian collaborations should be included on page 6 (question 23) of the Proposal Cover Booklet. The lead partner shall be the non-DOD agency. Questions regarding military/civilian collaborations should be directed to USAMRAA by fax: (301)619-2937.

IV-A.2. Procurement Integrity, Conflicts of Interest, and Other Improper Business Activities

The Procurement Integrity Act, Title 41 United States Code 423, et seq., contains prohibitions against certain activities between offerors and Government officials. Any questions regarding these prohibitions should be directed to the USAMRMC legal staff at (301)619-2065. Proposed military/civilian collaborations should pay special attention to the Procurement Integrity Act.

IV-B. Proposal

IV-B.1. Disclosure of Information Outside the Government

By submission of an application, the applicant understands that disclosure of information outside the Government shall be for the sole purpose of technical evaluation. The USAMRMC will obtain a written agreement from the evaluator that information in the proposal will only be used for evaluation purposes and will not be further disclosed or utilized.

IV-B.2. Award Eligibility

To be eligible for award, a prospective recipient must meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, and conformance with safety and environmental statutes and regulations (OMB Circular A-110).

IV-B.3. Government Obligation

Principal Investigators are cautioned that only an appointed Contracting Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government to fund preparation of a proposal or to support research should be inferred from technical discussions with a technical project officer. A Principal Investigator who or an organization that makes financial or other commitments for a research effort in the absence of an actual legal obligation signed by the USAMRMC Contracting Officer does so at their own risk.

IV-B.4. Information Service

Offerors may use the technical reference facilities of the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161, for the purpose of surveying existing knowledge and avoiding needless duplication of scientific and engineering efforts and the expenditure thereby represented. To the extent practical, all other sources should also be consulted for the same purpose.

IV-B.5. Proposal Submission Deadline

The submission deadline for all component projects solicited in this BAA is 17 December 1997 and will be strictly enforced.

All submissions must be received at the address listed in Section IV-B.6 no later than 4:00 p.m. Eastern Standard Time on 17 December 1997. Any proposal received after the exact time specified for receipt will not be considered unless it is received before award is made, and it:

1. was sent by mail and it is determined by the Government that late receipt was due solely to mishandling by the Government after receipt at the Government installation.

2. was sent by U.S. Postal Service Express Mail Next Day Delivery--Post Office to Addressee and postmarked no later than 5:00 p.m. on 16 December 1997.

3. was sent by other commercial overnight courier service and placed into their control no later than 5:00 p.m. on 16 December 1997.

Reminder: This specification is for all submissions.

IV-B.6. Proposal Copies/Submission Address

Thirty-one copies of the proposal, including one original, will be submitted to:

Commander
U.S. Army Medical Research and Materiel Command
ATTN: MCMR-PLF (NFRP BAA 97)
1076 Patchel Street
Fort Detrick, MD 21702-5024

Refer to Section III, "Proposal Preparation," and the appendices cited therein to ensure that all items have been addressed or completed.

If acknowledgment of proposal receipt is desired, enclose a self-addressed, stamped postcard with the proposal. The postcard should state the proposal title.

IV-B.7. Funding Instrument

The funding instrument for most awards to academic and nonprofit institutions under this BAA will be grants. Cooperative agreements may be used where appropriate.

Grants and cooperative agreements are used to fund basic research when the principal purpose of the award is to transfer funds to the recipient to stimulate and carry out relevant research rather than to acquire property or services for the direct benefit or use of the Department of Defense. Grants are used when substantial involvement is not anticipated between the USAMRMC and the recipient to accomplish the activity contemplated by the award. Cooperative agreements are used when substantial involvement is anticipated between the Government and the recipient. Grants or cooperative agreements awarded by the USAMRMC will contain, where appropriate, detailed special provisions concerning patent rights, rights to technical data and computer software, reporting

requirements, equal opportunity employment, care of laboratory animals, direct or indirect use of human subjects and anatomical substances, Good Laboratory Practices requirements, acquisition and disposition of equipment, and other requirements. More information on the above may be obtained by request from:

Director
U.S. Army Medical Research Acquisition Activity
ATTN: MCMR-AAA
Fort Detrick, MD 21702-5014
Fax: (301)619-2937

IV-C. Research Administration

IV-C.1. Deliverables

The grant or cooperative agreement will require the timely delivery of several reports during the research effort. The Recipient and the Principal Investigator must realize that reports are necessary for the USAMRMC to monitor progress. While a particular research project may call for some variation, the Principal Investigator should plan on a requirement that consists of:

a. an ANNUAL report (for each year of research except the final year) that presents a detailed summary of scientific issues and accomplishments; and

b. a FINAL report (submitted in the last year of the grant period) that details the findings and issues of the entire project.

A copy of the manuscript or subsequent reprints of any publications resulting from the research **must** be submitted to the USAMRMC.

IV-C.2. Equipment/Property

Title to equipment or other tangible property purchased with grant or cooperative agreement funds may be vested in nonprofit institutions of higher education or with nonprofit organizations whose primary purpose is the conduct of scientific research. Normally, title will vest in the recipient if vesting will facilitate scientific research performed by the institution or organization for the Government.

Commercial organizations, including nonprofit institutions, are expected to possess the necessary facilities and equipment to conduct the proposed research. Generally, no funds will be authorized for equipment acquisition.

IV-D. Other Publications

Investigators are strongly encouraged to publish their results in scientific literature. A copy of the manuscript or subsequent reprints of any publications resulting from the research **must** be submitted to the USAMRMC.